PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional) 12730-705 (PA-5351-RFB)

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On: March 22, 2011

Signature: /Janet A. Pioli/

Typed or printed name: Janet A. Pioli

Application Number	Filed
10/726,963	December 3, 2003

For: METHOD AND DEVICE FOR TREATING AORTIC DISSECTION

First Named Inventor David Ernest Hartley

Art Unit	Conf. No.	Examiner
3731	4386	Ryan J. Severson

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a Notice of Appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five(5) pages may be provided.

I am the:

☐ Applicant/Inventor.

☐ Assignee of record of the entire interest.
See 37 CFR 3.71. Certificate under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)

☒ Attorney or agent of record.
Registration number 35,323.

☐ Attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34. _____.

/Janet A. Pioli/
Signature

Janet A. Pioli
Typed or Printed Name

312-321-4200
Telephone number

March 22, 2011
Date

Note: Signatures of all inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.*

☐ *Total of _____ forms are submitted.

CERTIFICATE OF EFS FILING UNDER 37 CFR §1.8
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Date: March 22, 2011 Name: Janet A. Pioli, Reg. No. 35,323 Signature: /Janet A. Pioli/

Attorney Docket No. 12730/00705
Client Ref. No. PA-5351-RFB

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: David Ernest Hartley et al.
Serial No.: 10/726,963
Filing Date: December 3, 2003
For: METHOD AND DEVICE FOR TREATING AORTIC DISSECTION

Examiner: Ryan J. Severson
Group Art Unit No.: 3731
Confirmation No.: 4386

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicant requests review of the file of the above-identified application, for the reasons stated in the attached sheets. No amendments to the claims are filed with this request. Applicants also file a Notice of Appeal along with this request. No more than five (5) pages are provided. In the interest of space, only independent claim 24 is discussed.

I. Background

A. The Rejections

Claims 6, 7, 9 and 24 are pending in the application. Claim 24 is independent and claims 6, 7 and 9 depend from claim 24. This application has been pending for over **seven** years. In the Final Office Action dated December 22, 2010, ("Office Action"), the Examiner rejects claims 6, 9 and 24 under 35 USC 103(a) obvious over Brightbill (US 2003/0204245)(Brightbill) in view of Cox et al (US 5,824,040)(Cox), and claim 7 under 35 USC 103(a) as obvious over Brightbill in view of Cox and further in view of McNamara et al (US 6,004,347)(McNamara).

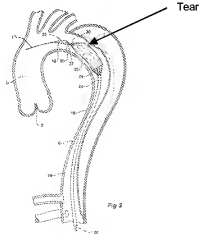
B. The Claimed Subject Matter

The presently claimed invention relates to a device for the treatment of aortic dissections. An aortic dissection is a tear in the intimal layer of the aorta which permits blood to flow through the tear and between the layers of the aorta and creating a false lumen. If not immediately treated, the dissection will result in rupture of the aorta and, invariably, in death. In some instances, the false lumen extends so far that a second tear further down the aorta is created.

Claim 24 is independent. In its current state, independent claim 24 recites an aortic dissection treatment prosthesis and requires at least:

1. a proximal covered portion;
2. a distal uncovered portion that is attached to and extends distally from the proximal covered portion;
2. the proximal covered portion comprising a tubular body of a biocompatible graft material and at least three self expanding stents within the tubular body and supporting the tubular body to provide an **outside sealing surface**;
3. the **distal uncovered portion** comprising **8 to 10 uncovered self expanding stents linked together** at their bends by flexible thread or fiber links and defining an elongate substantially cylindrical and **flexible lumen wall engaging surface**;
4. the flexible links comprising a thread or fiber connected between adjacent stents in the uncovered stent assembly;
5. the proximal **covered portion providing a cover for an aortic dissection** to close off the dissection so that blood can no longer flow therethrough **and the distal uncovered portion providing gradual pressure to close** a false lumen of the aortic dissection and open up a true lumen with the **flexible links between adjacent bends of the stents enabling each stent to expand separately as the false lumen is closed off**.

Figures 3 and 4, reproduced below, exemplify the claimed invention.



As shown, the tear is sealed by component 25, the proximal covered portion. With the tear sealed, the false lumen--the bubble on the right hand side of the aorta, is sealed. The uncovered stented portion provides pressure on the wall of the false lumen away from the rupture. Due to the sealing portion and the pressure providing portion the device cooperates to collapse the false lumen and prevent rupture of the aorta, hence, saving the life of the patient.

II. The Rejection of the Claims Is Improper

The Examiner relies on two references (Brightbill and Cox) for his obviousness rejection of claims 6, 9 and 24. The Examiner's reliance is misplaced. Neither reference nor their combination discloses or suggests at least **6** claim elements. No combination of the disclosures of Brightbill or Cox disclose the claimed subject matter arranged in the manner as claimed. The Examiner provides no logical rationale as to why one of ordinary skill in the art would have taken the linkages shown in Figure 7E of Cox to use on the Brightbill stent. Appellants submit there is no rationale for doing so. Further, the Examiner's requirement that Appellants show criticality of the number of stents in the uncovered portion improperly shifts the burden onto Appellants. Finally, the Examiner has engaged in impermissible hindsight as nothing relied on by the Examiner results in the claimed combination without the resort to Appellants' specification.

A. The Examiner Fails to Account For Numerous Claim Elements

The Examiner concedes that Brightbill does not disclose two of claim elements-- 8-10 uncovered individual stents linked together by flexible links. The Examiner concedes that Cox does not disclose 8-10 uncovered individual stents linked together. In addition to these deficiencies, neither reference, alone or in combination, discloses:

- a covered **proximal** portion having an **outside sealing surface and** a uncovered distal portion;
- an uncovered distal portion having a **flexible lumen wall engaging surface**;
- the **distal uncovered portion providing gradual pressure to close a false lumen**; **and**
- the **flexible links between adjacent bends of the stents enabling each stent to expand separately as the false lumen is closed off**.

The Examiner simply fails to address these missing elements. For this reason alone, the Examiner fails to establish *prima facie* obviousness.

B. The Examiner Improperly ShiftsThe Burden To Appellants

The Examiner argues that Appellants have not shown criticality of the 8-10 uncovered linked stents. This rejoinder by the Examiner improperly shifts the burden to Appellants to establish criticality for the aluminum without furnishing a persuasive rationale explaining why one of ordinary skill in the art would have "created the prosthesis of Brightbill with 8-10 uncovered stents instead of two," as the Examiner asserts. *See Ex Parte Michael T. Morman, Patricia H. Calhoun, and James M. Carr*, 2010 WL 3626550 (Bd.Pat.App. & Interf. 2010).

Brightbill is not concerned with providing a length of self-expanding uncovered stents for the purposes of providing pressure on vessel to close a false lumen, but only for providing a vehicle for the delivery of therapeutic agent. Cox does not make up for this deficiency as Cox, at Figure 7E relied on by the Examiner, shows only stents having an inner liner. For this reason, the Examiner's rejection is wholly improper and must be reversed.

Notwithstanding these deficiencies, Appellants **have** explained the importance of the number of uncovered stents. The false lumen, which may run the length of the aorta, must be collapsed without obstructing the number of intercoastal arteries that run the length of the aorta. Hence, the length of the uncovered portion must be at least as long as the false lumen **and** not obstruct branch arteries. To do anything other would be potentially fatal to the patient. For this reason also, the Examiner's rejection is wholly improper and must be reversed.

C. No Combination of the Cited References Arrives at The Claimed Subject Matter Arranged in the Manner as Claimed

The Examiner also has not shown how the combination arrives at the Appellants' invention as arranged in the manner claimed. For the sake of argument, without concession, Brightbill discloses that some part of the single stent may have a sheath and some part of it will not. Figure 7E of Cox, relied on by the Examiner, and the accompanying text, show linked stents, but as clearly set forth at column 13, lines 28-30, the embodiments for Figure 7 (A-G) have an **inner** liner 112. Cox does not show or disclose a plurality of **uncovered** stents that are linked, but stents having an **inner** liner. The Examiner does not provide any rational underpinnings for why one of ordinary skill would remove the inner liner of the relied upon Cox

embodiment and take the then unlined device and substitute it for the uncovered unitary stent of Brightbill. They would not.

Brightbill is not concerned with flexibility, but only the delivery of a drug to a target area. Cox is not concerned with delivery of a drug to a target area. Thus the Examiner must rely on various features from the individual embodiments of the references and modify them so that the embodiments can be combined. *See Ex Parte Michael T. Morman*, 2010 WL 3626550 (Bd.Pat.App. & Interf. 2010). The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification. There is no such suggested desirability. *See, Ex Parte Bernhard Graute, Eckhard Hellmer, and Joerg Kempe*, 2010 WL 3768165, *2(Bd.Pat.App. & Interf. 2010).

The Examiner has not articulated reasoning with rational underpinning, i.e., related to the concerns addressed by each of the references and the claimed invention, as to why one of ordinary skill in the art would pick and choose various features from the individual embodiments to construct the claimed subject matter as laid out in the claim. For this reason also, the rejection is improper.

D. The Examiner Has Engaged In Impermissible Hindsight

Finally, notwithstanding the Examiner's denials, he has engaged in impermissible hindsight. Indeed, the Examiner points to no suggestion in Brightbill to use a plurality of using flexibly linked uncovered stents, and points to no suggestion in Cox that the covered linked stents disclosed therein can be used for Brightbill's purposes. *See, Ex Parte Bernhard Graute, Eckhard Hellmer, and Joerg Kempe*, 2010 WL 3768165, *2(Bd.Pat.App. & Interf. 2010). Because the Examiner has not articulated reasoning with rational underpinnings to modify each of the references in some way and then combine them, without the benefit of Appellants' disclosure, hindsight must be inferred.

For at least these reasons, and those set forth in Appellant's previous responses, the rejections of the claims should be withdrawn and the claims allowed.

Respectfully submitted,

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